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(54) Apparatus for vein removal

(57) An instrument for harvesting a section of vein for use in a different environment comprises an elongated central rod 10, to support the vein being harvested and guide a cutting element 20, the tubular cutting element having a cutter head 22 which can be passed along the rod-supported vein and rotated to cut the vein free from surrounding tissue, access to the vein being provided by a first incision, through which the rod and cutting element are introduced to the vein, and a second incision through which the second end of the vein section is cut and ligated. The instrument containing the vein section and central rod can be withdrawn through the first incision.

Fig.1.

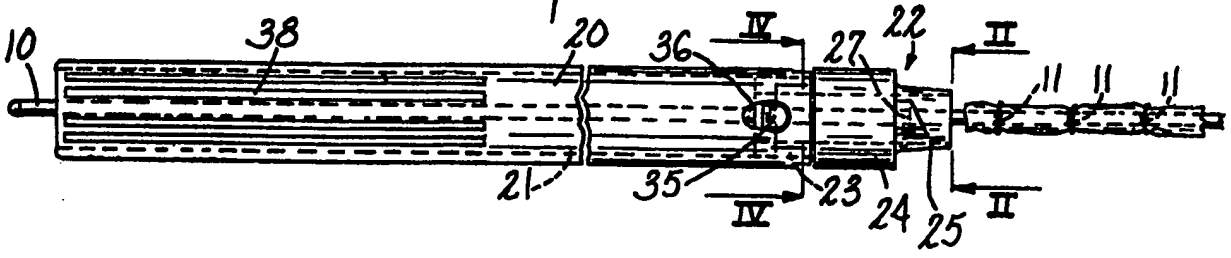

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Fig.1.

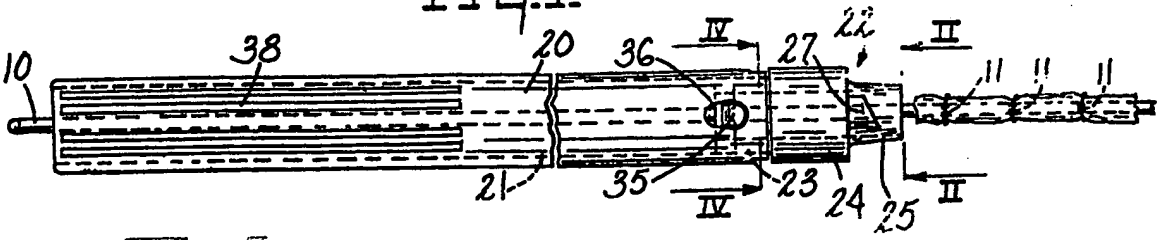


Fig.2.

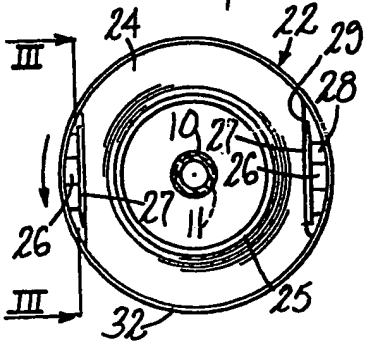


Fig.3.

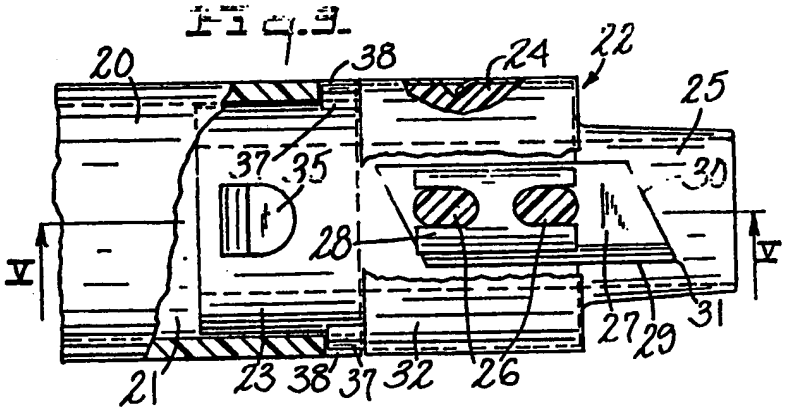


Fig.4.

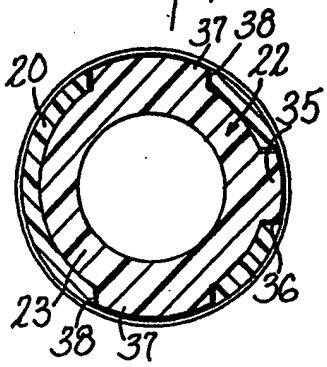


Fig.5.

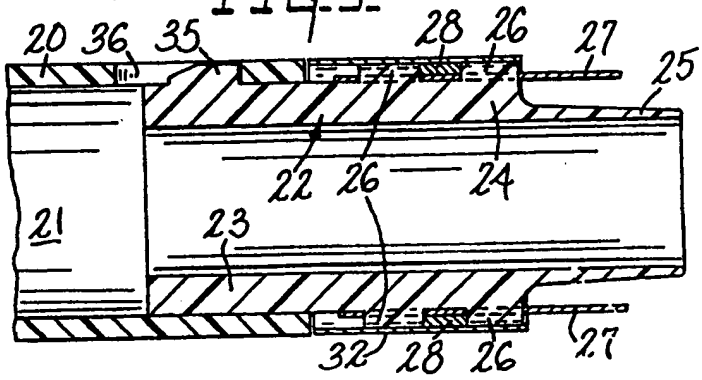


Fig.6.

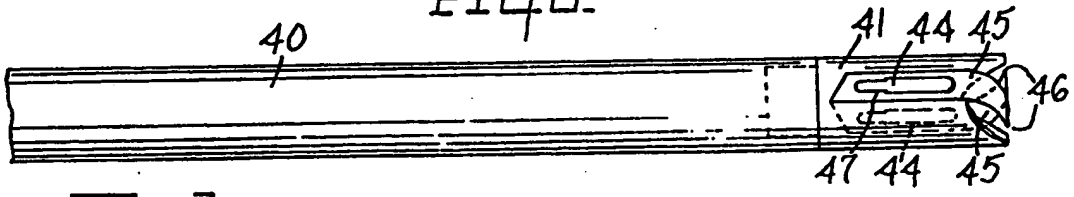


Fig.7.

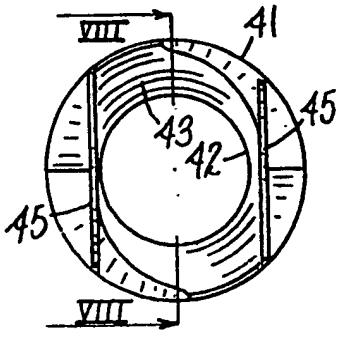
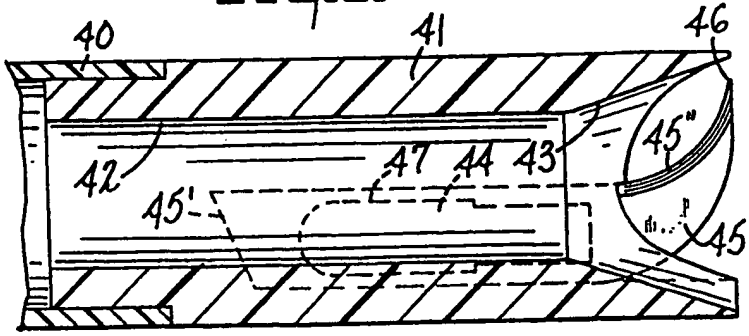


Fig.8.



SPECIFICATION

Improvements in or relating to vein removal

This invention relates to a method and instrument for harvesting a section of vein for use in a different environment.

The autogenous saphenous vein is widely used in reconstructive vascular surgery. Indeed, it is about the only successful arterial substitute available for use in coronary artery bypass surgery and in the vast majority of peripheral vascular reconstructive procedures. All of these procedures being by harvesting a desired length of the saphenous vein which is accomplished through either multiple incisions on the medial side of the thigh and leg or through a simple long incision extending from the groin to some point toward or below the knee. The vein is then dissected free and removed. The multiple incisions or one long incision are then repaired, after which, the vein is prepared for the reconstructive vascular surgery by ligating tributaries, dissection of the adventitia from the vein and distention with saline injected under pressure. Obviously, the harvesting of the vein is a very time-consuming procedure, requiring one or multiple incisions along the medial aspect of the lower extremity, leaving disfiguring scars and often areas of skin breakdown related to the surgical manuevers necessary to harvest the vein.

It is accordingly an object of the invention to provide an instrument which can be used to harvest the saphenous vein in an operation which requires only two small incisions.

It is another object of the invention to provide an instrument which can be actuated to remove the saphenous vein in sound condition for use as required.

According to the invention there is provided the method of harvesting a section of vein as living tissue for use in a different environment which includes the steps of

providing an instrument comprising a central rod element and a tubular cutting element having a distally located cutting head provided with at least one blade adapted to cut tissue along a helical path, the lumen of said cutting element being sized to receive the vein and the rod element, and the rod element being at least twice as long as the cutting element; making a first incision at a point corresponding to a first end of the vein section to be harvested;

inserting the rod element into the vein through said incision to a distance corresponding to the length of the desired vein section;

securing said first vein end to the rod element at a point intermediate to the ends of the latter;

passing the cutting element over the free head into said first incision;

rotating and advancing the cutting element along the rod element as a guide while causing the cutting head to separate the vein from surrounding tissue;

making a second incision at a point corresponding to a second end of the vein section to be harvested;

cutting the vein at said second end; and

withdrawing the instrument and enclosed severed vein through said first incision.

According to the invention there is also provided a vein harvesting instrument comprising a central rod element adapted to be passed through the lumen of a vein to be harvested, and a tubular cutting element having a distally located cylindrical cutting head;

the cutting head having a lumen sized to receive the vein and central rod, and a distal portion of the cutting head lying in a first plane defining the distal terminus of the cutting element;

at least one flat cutting blade fixed in the cutting head and lying in a second plane parallel to the axis of said element, the blade having a point which extends distally no farther than the said first plane;

the tubular cutting element having a length at least equal to the length of the vein portion to be harvested; and

the central rod having a length more than twice that of the cutting element.

By using a preferred form of instrument and procedure according to the invention one person can remove the entire saphenous vein in a few minutes, contrasted with the time of one or two hours now required for conventional methods.

Suitably, the instrument is relatively simple to manufacture and hence can be considered disposable.

Since the procedure disclosed herein has some mechanical similarity to vein stripping, numerous prior instruments for that purpose have been noted. A very significant difference is that veins are normally stripped in order to get rid of varicosities or other defects, whereas the present method is concerned with the careful removal of a healthy vein in good condition for continued use in a different environment, e.g. in bypass surgery. The vein stripper patents which have been considered are U.S. Patents Nos 2,661,003 (Devine et al), 2,863,458 (Modny et al), 2,868,206 (Stoesser), 3,045,676 (Slaton), 3,508,553 (Kanbar et al), 3,568,677 (Nolan et al), 3,659,606 (Reimels) and 3,788,325 (Jacobsen).

A publication referring to vein stripping with an instrument somewhat similar to that shown in the *Stoesser* patent, above, is Surgery, Vol. 20, pages 271–275 (1975) article by Kutz and Hendricks entitled "New Vein Stripper and Technique of Stripping".

Nowhere in the prior art known to applicant

is there any suggestion of the method and instrument for removal of a section of the saphenous vein in stretched out condition, supported on a rod and enclosed within a tube, in condition for use as needed, e.g. for bypasses.

The invention will now be described, by way of example, with reference to the accompanying drawings, wherein:–

Figure 1 is a side elevation of instrument according to the invention, parts being broken away to show interior elements;

Figure 2 is an enlarged detail section on the line II–II of Fig. 1;

Figure 3 is an enlarged detail section on the line III–III of Fig. 2;

Figure 4 is an enlarged transverse section on the line IV–IV of Fig. 1;

Figure 5 is an enlarged detail axial section on the line V–V of Fig. 3;

Figure 6 is an elevation of a modified form of instrument according to the invention;

Figure 7 ia an enlarged end view of the head end of the instrument, from the right of Fig. 6; and

Figure 8 is an enlarged axial section on the line VIII–VIII of Fig. 7.

Referring to the drawings, particularly Figs. 1 to 5 thereof, the instrument comprises two components, namely, a central rod and a separate cutting instrument.

The central rod 10, which serves as a mandrel on which the vein being removed is supported and maintained in elongated form may suitably be of medical grade nylon having a diameter of about 3 mm. and a length of 105 cm. which is more than twice the length (50 cm.) of the cutting instrument. At and near a mid-point in its length the rod is provided with one or more (three being shown) annular grooves 11 in its outer surface, the grooves being spaced at intervals of about 1 to 2 cm.

The cutting element, as shown in Figs. 1 to 5, comprises a tubular body 20, of a suitable smooth plastic material having an outside diameter no greater than 15 mm. and a lumen 21 of about 7 mm diameter. At one end a cutter head 22 is provided, the cutter head being cylindrical, with a base end 23 secured in the distal end of the body 20, an intermediate blade-mounting portion 24, and a distally projecting nose portion 25. The intermediate portion is shown as having opposite sides flattened and provided with one or more bosses 26 which engage in slots or holes formed in the steel cutting blades 27, two of which are shown; H-shaped fillers 28 assist in retaining the blades in position. Each blade has a cutting edge 29, lying parallel to the axis of the head, and a non-cutting forward edge 30 which is angled rearwardly from the distal point 31. The blades may suitably be secured on the cutter head by means of a cylindrical ferrule 32, of steel or plastic. The nose portion 25 of the cutter head is cylindrical and tapers slightly as it projects a short distance (e.g. 3 mm.) distally beyond the points 31 of the blades. The cutter head assembly is shown as being locked into the body 20 by means of a lug 35 on the base end 23 which can be snapped into the opening 36 to provide a mechanical lock in addition to cement or other securing means, if desired. The stability of the cutter head is further assured by the provision of additional radial lugs 37 at the forward end of the base 23 which fit in recesses 38 in the distal edge of the body 20.

Adjacent its proximal end the body 20 has a finger-grip area 38 which may be ridged or knurled for a convenient distance in order to facilitate the manual rotation of the cutter in performance of its intended function.

The modified form of cutting element, shown in Figs. 6, 7, and 8, comprises a tubular body 40 (like the body 20) on the distal end of which is mounted a cutter head 41, of cylindrical form, with a lumen 42 and a funnel shaped forward opening 43, opposite sides of which are cut away to provide sockets and supporting lugs 44 for the blades 45. Each of the two blades has a straight shank portion 45′ and a cutting portion 45″, the latter curving inwardly and rearwardly from the point 46. The elongated slots 47 in the shank portions of the blades fit snugly on the lugs 44 to retain the blades securely in cutting position. The proximal end of the body 40 is provided with a finger grip (not shown) like the area 38, for manual rotation of the cutting element, and the same central rod 10 is used with each cutting element.

In use, for removal of the saphenous vein, the recommended procedure involves cutting down on the vein at two points, a first one below the knee and a second one at a selected point in the groin. At the first point the vein below the knee is ligated and divided. The plastic central rod 10 is introduced into the saphenous vein and passed up within the lumen of the vein until it cn be palpated at the groin. The cut lower end of the vein is then tied securely to one or more of the grooves 11, to keep the vein extended and prevent it from slipping during the removal process.

The cutting element is then introduced over the projecting end of the plastic rod (only half of which is in the lumen of the vein) and passed along the course of the saphenous vein toward the groin. The sharp blades in the cylindrical head of the cutting element cut the tributaries and fatty tissues about the vein as the cutting element is rotated and passed toward and groin. The plastic rod centers the saphenous vein and insures that the cutting tool will follow the course of the saphenous vein to the groin.

The projecting nose portion 25 of the cutter

head 22 effectively guards the vein from contact with the blades 27 while presenting the surrounding tissue to the blades in somewhat tensed condition for accuracy of cutting. In the instrument of Figs. 6 to 8 the edges of the opening 43 deform the tissue surrounding the vein in such a way as to present cuttable surfaces to the blades 45, spaced from the vein which lies in the lumen 42 of the cutter head.

When the cutting head reaches the groin, the vein is ligated and divided, after which, the entire instrument, with the vein supported on the rod 10 and enclosed within the tubular body 20 (or 40) is removed through the first incision. The two small incisions are closed and an elastic dressing applied to the thigh to control bleeding as it is routinely done for saphenous vein stripping procedures. The vein is thus removed in a very brief period of time, after which it is prepared for use in bypass surgery in the usual fashion.

This entire procedure can be done by one individual. Based upon experiments with elementary prototypes, one can remove the entire saphenous vein in less than five mintues as compared to the one to two hours involved in the technique currently used in most institutions as described in the "BACKGROUND" paragraph above.

The central rod, which serves as a support for the vein and a guide to the cutting head, must be greater than twice the length of the cutting tool. It is important that after tying the saphenous vein to the central rod, the rod should be pulled upon so as to exert slight tension on the vein as the cutting tool is pushed toward the groin to insure that the vein does not fold and accidentally become caught in the cutting element.

It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in carrying out the above method and in the constructions set forth without departing from the spirit and scope of the invention, it is intended that all matter contained in the above description and shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

CLAIMS

1. The method of harvesting a section of vein as living tissue for use in a different environment which includes the steps of—

providing an instrument comprising a central rod element and a tubular cutting element having a distally located cutting head provided with a least one blade adapted to cut tissue along a helical path, the lumen of said cutting element being sized to receive the vein and the rod element, and the rod element being at least twice as long as the cutting element;

making a first incision at a point corresponding to a first end of the vein section to be harvested;

inserting the rod element into the vein through said incision to a distance corresponding to the length of the desired vein section;

securing said first vein end to the rod element at a point intermediate to the ends of the latter;

passing the cutting element over the free end of the rod element to bring the cutter head into said first incision;

rotating and advancing the cutting element along the rod element as a guide while causing the cutting head to separate the vein from surrounding tissue;

making a second incision at a point corresponding to a second end of the vein section to be harvested;

cutting the vein at said second end; and

withdrawing the instrument and enclosed severed vein through said first incision.

2. The method of harvesting a vein according to claim 1 which includes the step of applying tension to the vein after its end is secured to the rod.

3. The method of harvesting a vein according to No. 1 wherein the vein is a saphenous vein to be used in establishing one or more bypasses.

4. A vein harvesting instrument comprising a central rod element adapted to be passed through the lumen of a vein to be harvested, and a tubular cutting element having a distally located cylindrical cutting head;

the cutting head having a lumen sized to receive the vein and central rod, and a distal portion of the cutting head lying in a first plane defining the distal terminus of the cutting element,

at least one flat cutting blade fixed in the cutting head and lying in a second plane parallel to the axis of said element, the blade having a point which extends distally no farther than the said first plane,

the tubular cutting element having a length at least equal to the length of the vein portion to be harvested, and

The central rod having a length more than twice that of the cutting element.

5. A vein harvesting instrument according to claim 4 wherein the central rod element is provided with at least one annular groove adjacent the mid-point of the rod.

6. A vein harvesting instrument according to claim 4 wherein there are two cutting blades, each having a cutting edge facing substantially tangentially of the cutting head.

7. A vein harvesting instrument according to claim 6 wherein the cutting blade edges are straight and lie substantially parallel to the axis of the cutting head.

8. A vein harvesting instrument according to claim 6 wherein the cutting edges are

curved.

9. The method of harvesting a section of vein as living tissue for use in a different environment substantially as hereinbefore described with reference to, and as illustrated in, the accompanying drawings.

10. A vein harvesting instrument constructed, arranged and adapted to operate substantially as hereinbefore described with reference to, and as illustrated in, the accompanying drawings.

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